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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

February 18, 1997

WARNING LETTER
CIN-WL-97-181

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John H. Schindler, President
Broad Run Cheese House
6011 Old Route 39 N.W.
Dover, Ohio 44622

Dear Mr. Schindler:

The Food and Drug Administration (FDA) conducted an inspection of your swiss cheese manufacturing plant at Dover, Ohio on December 16-18, 1996. At the conclusion of the inspection, you were issued Form FDA-483, Inspectional Observations (copy attached) which listed a number of significant insanitary conditions present in your cheese plant at the time of that inspection. These conditions cause the swiss cheese manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (The Act).

The conditions included: the equipment used for producing cheese such as the make vats, drip vats and hand tools were not sanitized between uses; the sink used for hand washing empties directly on the floor in the baby swiss cheese make area; the employees were not always wearing proper attire (hairnets or apron), were not washing their hands after eating and drinking, and were eating and drinking coffee in the production room while working; unidentified animal droppings were observed directly outside the milk dumping room entrance where employees walk in and out of the plant; spray from a high pressure hose, used in cleaning a drip vat, was observed landing on in-process cheese being made in the make vats; and the employee dumping the milk cans was not routinely examining the contents or smelling the milk before dumping.

Furthermore, FDA's microbial analysis of in-line samples collected during the inspection showed E. Coli in sample of cream collected after heat treatment; milk after the separator as it was entering the make vat; cheese material from the inside wall of the brine tank; whey and curd after the make process is complete; and in the brine solution from the brine tank.

Microbial analysis of two samples of baby swiss cheese collected during the inspection found E. Coli levels greater than $1X10^4$ per gram of product. This microbial contamination causes your baby swiss cheese to be adulterated within the meaning as Section 402(a)(3) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure injunction and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

LEB/clc

Attachment